



Declaration of Conformity

1. Manufacturer:

Name: Zhende Medical Co.,Ltd
Address: Gaobu Town, 312035, Shaoxing, Zhejiang, China
SRN: CN-MF-000009961

2. European Representative:

Name: Shanghai international Holding Corp.GmbH(Europe)
Address: Eiffestraße 80, 20537 Hamburg, Germany.

3. Notified Body:

Name: TÜV SÜD Product Service GmbH, Ridlerstr, 65, 80339 München, Germany
Identification number: 0123

4. Product Name: Non-sterile Ostomy Appliances

Basic UDI-DI: 69593857NOA000001AJ

5. Intended use: Non-sterile Ostomy Appliances are used as a receptacle for collection of fecal material or urine. The Ostomy Appliances contact to stoma or otherwise compromised body surface. The device and its accessories includes the ostomy collection bag, ostomy paste, ostomy powder, ostomy mouldable ring, elastic tape, solidifying agent and so on.

6. EMDN Code: A1001/ A1002/ A100302/ A108001/ A108002/ A108003/ A108004 /A108005/ A108006/ A108099

7. Classification: Class I non-sterile

Based on MDR EU2017/745 Annex VIII rule 4:

All non-invasive devices which come into contact with injured skin or mucous membrane are classified as: class I if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates.

8. Statement: We declare the compliance of the above medical device with the applicable requirements of Medical Device Regulation: REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices. The EU declaration of conformity is issued under the sole responsibility of Zhende Medical Co., Ltd.

9. Common Specification: NA


10. Standard Applied:

EN ISO 15223-1:2021

EN ISO 13485:2016

EN ISO 14971:2019

Place, Date of Issue: Shaoxing,Zhejiang. 2022.7.29

Signature: 

Name: Chen Ming

Position:Regulatory Director



Product List

S/N	REF	Product name	Description
1	2022483	Ally Rings	diameter 48mm, thickness 3mm
2	2022484	Ally Rings	diameter 48mm, thickness 4.5mm
3	2022983	Ally Rings	diameter 98mm, thickness 3mm
4	2022100	Ally Powder	28g/bottle
5	2022200	Ally Paste	80g/tube
6	2022300	Ally Wafer Extenders	R: 80mm